



Atty. Dkt. No. 016915-0287

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Petrus KARSTEN et al.

Title: SYNDIOTATIC POLYPROPYLENE COMPOSITION COMPRISING
A THERMOPLASTIC ELASTOMER

Appl. No.: 10/587,565

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DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Petrus Karsten, declare that:

1. I am Research & Development and New Business Development Manager of Renolit AG, the assignee of record in the above-captioned application, located at Horchheimer Strasse 50, 67547 Worms, Germany.

2. From 1981 to 1987 I studied chemistry and chemical and process technology at the University of Amsterdam, The Netherlands.

3. I worked for Solvay from 1988 to 2006. In 2006 I started working for Renolit. Since 1988 I have worked 15 years in research and development in polymer processing, chemistry and technology.

4. My field of specialty is polymer processing, chemistry and technology.
5. In 1995, I earned "Certified Polymer Scientist; RPK" from National Dutch Research School (PTN), and Dutch Polymer Institute (DPI), which is linked to the University of Eindhoven, The Netherlands. This is the highest possible title to achieve in polymer science.
6. Since 1995 I have worked in Medical Supplies, developing medical grade plastics for use in hospitals worldwide.
7. Since 1997 I am responsible for all research and development work regarding medical plastics worldwide, first at Solvay and now at Renolit.
8. Since 2003 I am also responsible for New Medical Business and Development, first at Solvay and now at Renolit.
9. I am a co-inventor in the above-captioned application.
10. A vinylisoprene unit stems from isoprene (2-methyl-1,3-butadiene). An isoprene unit is connected into the polymer chain with both double bonds of the butadiene and a vinylisoprene unit is connected into the polymer chain with one of the double bonds, as illustrated below:

11. Articles intended for medical applicants must meet strict requirements particular to the application, such as their ability to be subjected to a sterilization treatment, their flexibility, and their transparency.
12. As supported by the technical data set forth in more detail below, multilayer structures formed from polymers containing syndiotactic polypropylene resin and a thermoplastic elastomer containing vinylisoprene or butadiene units exhibit superior transparency properties over other polymers, even when subjected to steam sterilization.

13. Additionally, the improved properties of the multilayer structures formed from polymers containing syndiotactic polypropylene resin and a thermoplastic elastomer containing vinylisoprene or butadiene units are described within the description of the above-captioned application, particularly within the examples and comparative examples in the specification of the captioned patent application at page 10, line 18 – page 14, line 26.

14. Additional testing was completed using the following polymers:

- Syndiotactic polypropylene (s-PP) grade 1251 from Totalpetrochemicals with MFI2 according to ASTM D1238 and made by using a metallocene catalyst;
- Elastomer 1: SVIS, SI triblock polymer styrene-(vinylisoprene-co-isoprene)-styrene (the hydrogenated form is SVIHS which is grade Hybrar® 7125 from Kuraray);
- Elastomer 2: SIBS, SI triblock polymer styrene-(isoprene-co-butadiene)-styrene (the hydrogenated form is SEPBS which is grade Kraton® G 1730 from Kraton);
- Elastomer 3: SIS, SI triblock polymer styrene-1,4-isoprene-styrene (the hydrogenated form is SEPS which is grade Septon® from Kuraray);
- Elastomer 4: SBS, SB triblock polymer styrene-(butadiene)-styrene (the hydrogenated form is SEBS which is grade Kraton® 1726 from Kraton).

15. Twelve mixtures of 20, 50, or 80% syndiotactic polypropylene (s-PP 1251) with the four elastomers were prepared, as detailed in Table 1, below:

Table 1:

s-PP 1251 (%)	Elastomer	Elastomer (%)
80%	Elastomer 1 - Hybrar [®] 7125	20%
50%	Elastomer 1 - Hybrar [®] 7125	50%
20%	Elastomer 1 - Hybrar [®] 7125	80%
80%	Elastomer 2 - Kraton [®] G1730	20%
50%	Elastomer 2 - Kraton [®] G1730	50%
20%	Elastomer 2 - Kraton [®] G1730	80%
80%	Elastomer 3 - Kraton [®] G1726	20%
50%	Elastomer 3 - Kraton [®] G1726	50%
20%	Elastomer 3 - Kraton [®] G1726	80%
80%	Elastomer 4 - Septon [®] 2004	20%
50%	Elastomer 4 - Septon [®] 2004	50%
20%	Elastomer 4 - Septon [®] 2004	80%

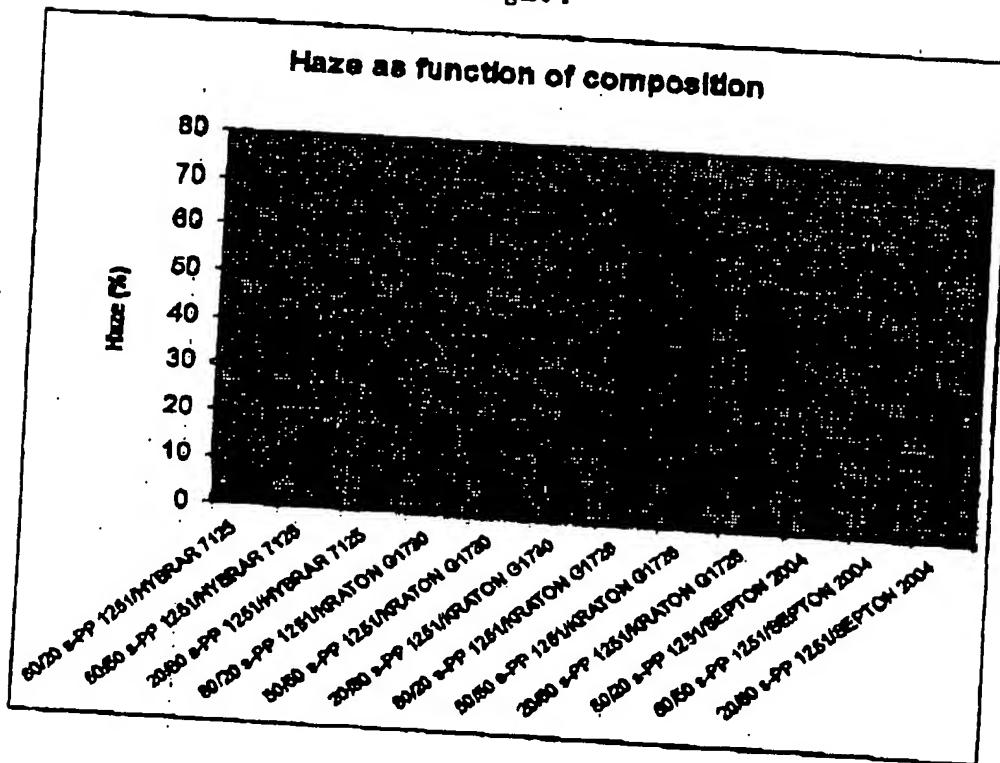
16. The mixtures were tumbled and then extruded into rods of 5 mm diameter on a single screw 45 mm extruder at a constant speed of 30 rpm and at a constant temperature setting (barrel: 140, 200, 200°C and die head at 200°C). The rods were then cooled in a water bath and pulled at a constant speed. From the mixtures, the rods were pressed at 170°C into thin sheets of 400 µm.

17. Haze was measured on the thin sheets using a calibrated Haze Guard device (according to ASTM D1003). The results are listed in Table 2 and illustrated in Figure 1, below:

Table 2

Composition	Haze (%)
80/20 s-PP 1251/Hybrar® 7125	12.3
50/50 s-PP 1251/Hybrar® 7125	16.2
20/80 s-PP 1251/Hybrar® 7125	11.7
80/20 s-PP 1251/Kraton® G1730	21.0
50/50 s-PP 1251/Kraton® G1730	16.7
20/80 s-PP 1251/Kraton® G1730	12.1
80/20 s-PP 1251/Kraton® G1726	70.8
50/50 s-PP 1251/Kraton® G1726	58.4
20/80 s-PP 1251/Kraton® G1726	52.2
80/20 s-PP 1251/Septon® 2004	20.3
50/50 s-PP 1251/Septon® 2004	21.4
20/80 s-PP 1251/Septon® 2004	28.7

Figure 1



18. As illustrated in Table 2 and the Figure, the compositions containing s-PP/Hybrar® 7125 and s-PP/ Kraton® G1730 have a significantly lower haze as compared to the s-PP/Kraton® G1726 and s-PP/Septon® 2004 compositions.

19. The rods were tested to investigate their tensile properties. The rods were cut to a length of 10 cm and placed between the two clamps of a tensile tester. The distance between the clamps was set precisely at 5 cm. The clamps moved with a speed of 500 mm/min to a maximum distance of 500 mm. The peak load and elongation at break was measured. The results are listed below in Table 3:

Table 3

Composition	Peak Load	Elongation at break
80/20 s-PP 1251/Hybrar® 7125	85.9	340
80/20 s-PP 1251/Kraton® G1730	92.3	280
80/20 s-PP 1251/Kraton® G1726	77.4	370
80/20 s-PP 1251/Septon® 2004	76	400
20/80 s-PP 1251/Hybrar® 7125	49.8	>500
20/80 s-PP 1251/Kraton® G1730	71.6	>500
20/80 s-PP 1251/Kraton® G1726	40.6	430
20/80 s-PP 1251/Septon® 2004	48.1	250

20. The 80/20 blends of the compositions containing s-PP/Hybrar® 7125 and s-PP/ Kraton® G1730 show a much higher peak load than the s-PP/Kraton® G1726 and s-PP/Septon® 2004 compositions, signifying a higher stiffness.

21. The 20/80 blends of the compositions containing s-PP/Hybrar® 7125 and s-PP/ Kraton® G1730 show a much higher elongation than the s-PP/Kraton® G1726 and s-PP/Septon® 2004 compositions, signifying improved compatibility.

22. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

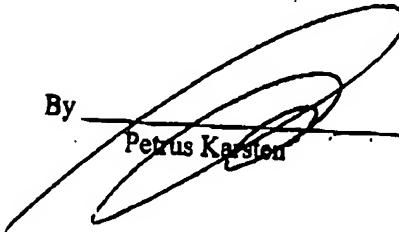
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United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date

16 - July - 2008

By


Petrus Karsten